Supreme Court, U.S.
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No. 91-300

IN THE
Supreme Court of the United States
OCTOBER TERM, 1991

NATIONAL ASSOCIATION OF
PHARMACEUTICAL MANUFACTURERS,
Petitioner,

v.

LOUIS W. SULLIVAN,
Secretary of Health and Human Services, *et al.*,
Respondents.

On Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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MEMORANDUM IN RESPONSE TO CROSS-PETITION FOR CERTIORARI

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MEMORANDUM IN RESPONSE TO CROSS-PETITION FOR CERTIORARI

Barr Laboratories, Inc. ("Barr")[1] is the petitioner in No. 91-81 and a respondent here. Barr concurs in the request of cross-petitioner National Association of Pharmaceutical Manufacturers ("NAPM") that this Court issue a writ of certiorari to review the judgment of the Court of Appeals for the District of Columbia Circuit.

As for the merits, Barr is not averse to a decision that requires the Food and Drug Administration to review *all* abbreviated new drug applications within the 180-day period established by 21 U.S.C. § 355(j)(4)(A).

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[1] Barr Laboratories, Inc. has no parent or subsidiary companies.

Barr points out, though, that in the event *Heckler v. Day*, 467 U.S. 104 (1984), is read to bar relief for the class represented by NAPM, that case does not preclude relief for Barr as an individual party.

Heckler v. Day was a class action on behalf of Vermont residents who had been denied social security disability benefits and had suffered unreasonable delays in the processing of petitions for reconsideration and the scheduling of hearings on their claims. *Id.* at 107-08. The District Court issued an order in favor of the class requiring the Secretary of Health and Human Services to take the requisite actions within specified time periods after appropriate requests were made, *id.* at 109, and the Court of Appeals affirmed. *Id.* at 110.

The statute at issue in *Day* did not specify a time limit for the agency to take the actions in question. *Id.* at 110-11. The District Court nevertheless held that the statute required hearings within a reasonable time, namely 90 days for hearings and 180 days for reconsideration requests. *Id.* at 109-10.

Justice Powell's opinion for the Court found that the failure to specify time limits in the statute had been intentional on the part of Congress. *Id.* at 109-10, 119. Accordingly,

> it would be an unwarranted judicial intrusion into this pervasively regulated area for federal courts to issue injunctions imposing deadlines with respect to future disability claims.

Id. at 119. In a footnote, however, the Court stated that "nothing in this opinion precludes the proper use of injunctive relief to remedy *individual* violations of [the governing statute]." *Id.* at 119 n. 33 (emphasis in original).

This case differs from *Day* in several decisive respects. For one thing, the statute at issue here contains a stated

deadline for agency action. 21 U.S.C. § 355(j)(4)(A) (1988). Second, the Court of Appeals held that the 180-day deadline of section 355(j)(4)(A) is mandatory. Cross-Petition, App. 4a. For these reasons Barr believes that *Day*'s distinction between class and individual relief is inapplicable here, and that both Barr and NAPM's members should be granted relief. Should this Court disagree on that point and decide that relief for the class represented by NAPM is not appropriate, the Court nevertheless should order relief for Barr as an individual aggrieved party.

Respectfully submitted,

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